



NFPA

The Food Safety People

NATIONAL

FOOD

PROCESSORS

ASSOCIATION

January 19, 2001

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No. 94P-0036] Food Labeling: *Trans* Fatty Acids in
Nutrition Labeling, Nutrient Content Claims, and Health Claims;
Reopening of Comment Period.
65 Federal Register 75888, December 5, 2000.

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Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above. NFPA previously filed comments to this docket in April 2000.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

On December 5, 2000 (65 FR 75888), FDA reopened the comment period on its *trans* fatty acids labeling proposed rule to allow for additional comment on two issues related to nutrient content claims: the possible definitions for a "reduced *trans* fat" claim and a "reduced saturated and *trans* fats" claim.

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NFPA commented relative to these claims in the April 2000 comments, and was noted by the Agency in the preamble to the December 5, 2000 reopening of the comment period as comment 2139, one of the comments that suggested the alternative nutrient content claims approaches that are the subject of the reopened comment period.

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In comments filed April 2000, NFPA wrote:

NFPA urges FDA to add a section of rule, §101.62(c)(7), which the Agency did not propose, representing criteria for a new “reduced *trans* fat” claim. Availability of this claim will permit food processors to reduce the amount of *trans* fat in their product formulations and notify consumers of this action. Criteria for this claim should consist of a minimum 25% reduction in *trans* fat content, and no increase in saturated fat content, compared to the reference food. If there are separate criteria for reduced *trans* fat, NFPA believes that the reduced saturated fat claims represented in proposed §101.62(c)(4)(i), should be similarly constructed, as a minimum 25% reduction in saturated fat with no increase in *trans* fat content, compared to the reference food.

If the FDA concludes, however, that a reduced *trans* fat claim should not be permitted, a majority of NFPA members believes that proposed §101.62(c)(4)(i) should be amended so that a reduced saturated fat claim could be permitted if the total saturated fat content, expressed as a combination of saturated fat and *trans* fat, is reduced by at least 25% compared to a reference food, regardless of whether the reduction is derived from modification of saturated fat content, *trans* fat content, or a combined reduction.

Consistent with the view we expressed in our previous comments, NFPA believes that it is essential for nutrient content claims related to saturated fat and *trans* fat to be authorized, to allow food processors to modify their food products and inform consumers of the improved nutritional characteristics. Food processors are committed to providing consumers with healthful and good tasting products, and are likewise committed to modifying foods to respond to consumers’ nutrition interests.

In order to achieve certain functional characteristics in foods, such as texture, some food processors formulate products with combinations of fats and oils that reflect a range of nutrient profiles for saturated fat and *trans* fat. When final rules are published mandating nutrition labeling with respect to *trans* fat, many of these food companies will wish to review their product formulations and adjust fatty acid profiles. Because of current product formulation practices, some flexibility will be required for such adjustments, and NFPA believes that nutrient content claims criteria should be compatible with this flexibility.

To achieve maximum flexibility in such nutrient content claims, NFPA now recommends that FDA develop definitions for a “reduced *trans* fat” claim, adopt amendments to the “reduced saturated fat” claim, and provide for a claim of combination reduction of *trans*

fat and saturated fat. Each claim could be utilized for specific types of modification to a product's fatty acid profile.

As NFPA noted in its April 2000 comments, a "reduced *trans* fat" nutrient content claim, will provide food processors with the incentive and the flexibility to reduce the amount of *trans* fat in a serving of food irrespective of any modification in saturated fat content. The criteria for the claim could be established so that the saturated fat content in the food cannot be increased to qualify for the "reduced *trans* fat" claim. Likewise, the supplementary information required for a "reduced" claim should include discrete information on both the quantitative *trans* fat and saturated fat content of the food, in comparison to the reference food. NFPA also believes it appropriate to limit the claim to foods where the reference food contains more than one gram of *trans* fat per reference amount, recognizing that the claim "low *trans* fat" has not been proposed.

In April 2000, NFPA commented that FDA should amend the criteria for a "reduced saturated fat" claim, contingent upon authorization of a "reduced *trans* fat" claim. NFPA believes that these two claims, with separate but complementary criteria, will provide food processors with the flexibility needed to make formula modifications and inform consumers of those changes. Separate criteria for a "reduced *trans* fat" claim would necessitate a parallel separate definition for "reduced saturated fat" that is only slightly different from the definition already established in 21 CFR 101.62(c)(4) and (5). Modifications would be needed first to ensure that a "reduced saturated fat" claim may not be used if the level of *trans* fat is increased relative to the reference food, and second to ensure that the supplementary claims information includes quantitative *trans* fat information relative to the reference food.

NFPA believes that there is merit for a nutrient content claim that characterizes a reduction in the combined amount of saturated fat and *trans* fat compared to a reference food. NFPA articulated in April 2000 comments that such a claim should be authorized if separate claims for "reduced *trans* fat" and "reduced saturated fat" are not authorized. Slightly modifying the approach articulated in our April 2000 comments, NFPA now believes such a claim could be authorized even if separate claims of "reduced *trans* fat" and "reduced saturated fat" also are permitted. A distinct claim would be needed because it is often the practice now in food labeling to couple one descriptive term with the names of several nutrients (e.g., "reduced fat and saturated fat"), with the understanding that such syntax implies that each nutrient qualifies for the claim separately, rather than through the combination of nutrients. The claim that NFPA suggests is "reduced combination of saturated and *trans* fat" or "reduced saturated/*trans* fat." This claim would allow for a flexibility in formulation changes, to achieve comparable performance characteristics while still allowing food processors to inform consumers about an overall reduction in the combination of *trans* fat and saturated fat. NFPA proposes that this combination claim be designated 21 CFR 101.62(c)(9) and (10).

The nutrient content claim amendments that NFPA advocates could be represented by the following regulatory language:

("Reduced saturated fat")

21 CFR 101.62 (c)(4) * * *

(ii) The amount of *trans* fat per reference amount customarily consumed is not increased above the level included in the appropriate reference food as described in §101.13(j)(1); and

(iii) As required in §101.13(j)(2) for relative claims:

* * *

(B) Quantitative information comparing the level of both saturated fat and *trans* fat in the product per labeled serving with that of the reference food that it replaces (e.g., "Saturated fat reduced from 3 g to 1.5 g per serving, *trans* fat content remains the same at 2 g") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

101.62 (c)(5) * * *

(ii) The amount of *trans* fat per reference amount customarily consumed is not increased above the level included in the appropriate reference food as described in §101.13(j)(1); and

(iii) As required in §101.13(j)(2) for relative claims:

* * *

(B) Quantitative information comparing the level of both saturated fat and *trans* fat in the product per specified weight with that of the reference food that it replaces (e.g., "Saturated fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz; *trans* fat remains the same at 2 g per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

("Reduced *trans* fat")

101.62(c)(7) The terms "reduced *trans* fat," "reduced in *trans* fat," "*trans* fat reduced," "less *trans* fat," "lower *trans* fat," or "lower in *trans* fat" may be used on the label or in the labeling of foods, except as limited by §101.13(j)(1)(i) and except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less *trans* fat per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and

(ii) The amount of saturated fat per reference amount customarily consumed is not increased above the level included in the appropriate reference food as described in §101.13(j)(1); and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the *trans* fat differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., "reduced *trans* fat. Contains 33 percent less *trans* fat than the national average for snack crackers."); and

(B) Quantitative information comparing the level of both *trans* fat and saturated fat in the product per labeled serving with that of the reference food that it replaces (e.g., "*Trans* fat reduced from 3 g to 2 g per serving; saturated fat remains the same at 2 g per serving") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iv) Claims described in paragraph (c)(7) of this section may not be made on the label or in the labeling of a food if the *trans* fat content of the reference food is one gram or less.

(8) The terms defined in paragraph (c)(7) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less *trans* fat per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and

(ii) The amount of saturated fat per reference amount customarily consumed is not increased above the level included in the appropriate reference food as described in §101.13(j)(1); and

(iii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food, and the percent (or fraction) that the *trans* fat differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced *trans* fat cheese pizza, "33 percent less *trans* fat per 3 oz serving than our regular cheese pizza").

(B) Quantitative information comparing the level of both *trans* fat and saturated fat in the product per specified weight with that of the reference food that it replaces (e.g., "*Trans* fat content has been reduced from 3 g per 3 oz serving to 2 g per 3 oz. serving; saturated fat content remains the same at 2 g per 3 oz serving") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iv) Claims described in paragraph (c)(8) of this section may not be made on the label or in the labeling of a food if the *trans* fat content of the reference food is one gram or less of *trans* fat per reference amount customarily consumed.

("Reduced saturated/*trans* fat")

101.62(c) * * *

(9) The terms "reduced combination of saturated fat and *trans* fat," "reduced saturated/*trans* fat," "combination of saturated fat and *trans* fat reduced," "saturated/*trans* fat reduced," "less combination of saturated fat and *trans* fat," "less saturated/*trans* fat," "lower combination of saturated fat and *trans* fat," "lower saturated/*trans* fat," or "lower in saturated-*trans* fat" may be used on the label or in the labeling of foods, except as limited by §101.13(j)(1)(i) and except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less of the combination of saturated fat and *trans* fat per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and

(ii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the combination of saturated fat and *trans* fat differs between the two foods are declared in immediate

proximity to the most prominent such claim (e.g., "reduced saturated-*trans* fat. Contains 33 percent less combination of saturated fat and *trans* fat than the national average for nondairy creamers"); and

(B) Quantitative information comparing the level of the combination of saturated fat and *trans* fat in the product per labeled serving with that of the reference food that it replaces (e.g., "Combined saturated fat and *trans* fat reduced from 3 g to 2 g per serving") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat" or the level of *trans* fat is one gram or less per reference amount customarily consumed.

(10) The terms defined in paragraph (c)(9) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less of the combination of saturated fat and *trans* fat per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and

(ii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food, and the percent (or fraction) that the combination of saturated fat and *trans* fat differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced saturated-*trans* fat Macaroni and Cheese, "33 percent less combination of saturated fat and *trans* fat per 3 oz than our regular Macaroni and Cheese").

(B) Quantitative information comparing the level of combined saturated fat and *trans* fat in the product per specified weight with that of the reference food that it replaces (e.g., "Combined saturated fat and *trans* fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (c)(10) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat" or if the *trans* fat content of the reference food is one gram or less per reference amount customarily consumed.

NFPA believes that all three nutrient content claims would be consistent with the proposed presentation of nutrition label information on *trans* fat that a majority of NFPA members supported in our April 2000 comments, especially if additional discrete information about saturated fat content per serving is permitted. In April 2000 comments, NFPA wrote:

Regarding presentation of nutrition information, in proposed §101.9(c)(2)(i)(B), the majority of NFPA members supports FDA's proposal that the footnote terminology state "includes" when *trans* fat is declared, to make clear to consumers they should not add a number to the Nutrition Facts declaration of saturated fat. "Contains" should be used only in optional statements that note no *trans* fat is present, as "contains" may suggest to consumers that they should otherwise add to the saturated fat declaration a quantity of *trans* fat that has already been added. A majority of NFPA members further recommend that the footnote for *trans* fat content include an option to declare grams of saturated fat, making it clear to consumers that two discrete values are combined for presentation in the saturated fat line of the nutrition label. (emphasis added)

In this manner, each nutrition label where *trans* fat was declared would also include information on the *trans* fat and saturated fat components represented in the combined declaration. The nutrition label thus would always provide reinforcing quantitative information consistent with the proposed "reduced" claims.

NFPA acknowledges that the presentation of *trans* fat information on the U.S. nutrition label has come under scrutiny in recent months, given the approach described by Canada in its recent consultation document on nutrition label format. NFPA commented to Canada in support of harmonized U.S.-Canada nutrition labeling, or mutual recognition; NFPA provided FDA with a copy of our comments to Canada. For the convenience of the Agency, we repeat below the comments we filed with Canada on the nutrition label format issue:

NFPA Members Support a Harmonized North American Food Label

Recently, the members of NFPA's International and Nutrition and Health Committees met and discussed Canada's proposed nutrition labeling format. Members of these two Committees represent over fifty food companies, some of which are multi-national with establishments in both the U.S. and Canada, and

most of which trade with Canada. These companies were generally supportive of the Canadian proposal and agree that most of the mandatory information on the nutrition label is material.

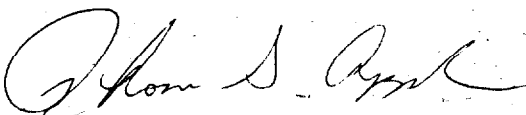
Most importantly, the companies are unanimous in their support for a harmonized U.S./Canada label format. In fact, many hope for a harmonized North American label. In that regard, NFPA commends Canada for proposing a label design that is very similar to the U.S. Nutrition Facts panel and for providing the flexibility to include, in U.S. format, those mandatory elements of the U.S. label that are proposed to be optional in Canada.

The most notable exception to a harmonized approach is the proposed labeling presentation for *trans* fat. FDA has proposed that the amount of *trans* fat be combined with saturated fat and be presented with an asterisk after saturated fat referring to a footnote on the *trans* amount within the saturated fat declaration, at the bottom of the panel. Canada proposes a separate line for *trans* fat but a combined Daily Value for saturated plus *trans*. In our recent discussion, NFPA member companies strongly agreed that the formats for U.S. and Canada should be consistent. Different presentation standards in the U.S. and Canada will be burdensome to manufacturers in both countries engaged in cross-border trade and would necessitate dual label inventories. In that regard, NFPA encourages both Health Canada and FDA to cooperate to harmonize the presentation approach or to provide the flexibility to permit either labeling approach in both countries.

NFPA in short believes that nutrition label format need not present an insurmountable impediment to permitting separate, specific nutrient content claims, as described, for saturated fat and *trans* fat.

Thank you for the opportunity to comment on this important issue.

Sincerely,



Rhona S. Applebaum, Ph.D.
Executive Vice President,
Scientific and Regulatory Affairs

CTTransClaimsRe